

on a yearly basis 7,743 importers will leave the market and 7,743 importers will enter the market.

#### *Hour Burden Estimate Researching the prior notice requirement*

To become familiar with the requirements for this rule, FDA estimates it will initially take responsible parties with Internet access (74,330 importers) about one hour to research the prior notice requirements and responsible parties without readily available Internet access (3,097 importers) about 2 hours to research the requirements. This one-time search burden for the existing importers is 80,524 hours.

In the years that follow the start-up year for prior notice, it is reasonable to expect a certain percentage of importing firms to enter and leave the market. Thus, in addition to the first year burden to research prior notice, it is expected that 8,053 hours will be spent annually researching the prior notice requirement by the anticipated 7,743 new importers entering the market annually that must learn about prior notice, 7,433 of whom are estimated to have Internet access and 310 of whom do not.

#### *Submitting prior notice*

To estimate the repetitive effort of submitting a prior notice, and updating and amending the information, as needed, FDA will assume the activity takes one hour each time an entry (based on an average of 2.6 lines, and therefore notices, per entry) must be submitted. This includes 45 minutes of an administrative worker's time to fill out the screen, including updating, and then 15 minutes of the manager's time to verify the information. FDA does not have information on how many prior notices will come from each of the 77,427 importers. However, we assume that 1,807,692 prior notices will be submitted annually (based on FY 2001 OASIS information); we can take this

number and divide by the 77,427 importers to get an average response frequency per importer of 23.3 notices.

#### *Secure storage and notifying FDA*

If an article of food is imported or offered for import with no prior notice or inadequate (e.g. untimely, inaccurate, or incomplete) prior notice, the food must be held at the port of entry or in a secure facility. In these cases, the submitter or carrier must promptly notify FDA of the location where the goods are held.

It is quite likely that more imported products will be held during the first year that the prior notice is required than in subsequent years as importers will learn from experience. Therefore, FDA estimates that imported products with insufficient prior notice will be held or sent to secure storage about 5 percent of the time during the first year and 2 percent of the time thereafter. This means that of the 1,807,692 prior notice entries received annually, in the first year prior notice is in effect we would expect 90,385 of the entries to be held or sent to secure storage; 36,154 entries would be held or sent to secure storage in subsequent years.

Most port storage facilities and secure storage facilities located at or near ports are probably familiar to submitters or carriers; therefore it should only take one-half hour per entry to notify FDA of the shipment's location. Thus, in the first year of the regulation, submitters or carriers will spend 45,193 hours notifying FDA of secure storage locations; 18,077 hours in subsequent years.

#### *Capital Cost and Operating and Maintenance Cost Burden*

Since all prior notices must be submitted electronically, we will assume that the 3,097 responsible parties without Internet access will have to purchase the appropriate IT equipment and gain Internet access to actually transmit the

information. Assuming computer equipment costs each firm \$2,000 and yearly Internet access costs each firm \$240 (\$20 per month for 12 months), this results in a one-time computer cost for these facilities of \$6,194,000 and a recurring Internet access cost of \$743,280. For the 7,743 new firms that enter the import market each year, we can expect 310 of them to need to purchase computer equipment and obtain Internet access. Thus, on an annual basis we can expect new importers to spend \$620,000 on computers and \$74,400 on Internet access to be able to submit prior notice information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, FDA Desk Officer.

## **VI. Analysis of Environmental Impact**

The agency has carefully considered the potential environmental effects of this action. FDA has concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## **VII. Federalism**

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the

distribution of power and responsibilities among the various levels of government. Accordingly, the agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive Order and, consequently, a federalism summary impact statement has not been prepared.

### **VIII. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA cannot be responsible for addressing comments submitted to the wrong docket or that do not contain a docket number. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FDA notes that the comment period for this document is shorter than the 75-day period that the agency customarily provides for proposed rules that are technical or sanitary or phytosanitary (SPS) measures. FDA believes that a 60-day comment period is appropriate in this instance. Executive Order 12889, "Implementation of the North American Free Trade Agreement" (58 FR 69681, December 30, 1993), states that any agency subject to the Administrative Procedure Act must provide a 75-day comment period for any proposed Federal technical regulation or any Federal SPS measure of general application. Executive Order 12889 provides an exception to the 75-day comment period where the United States considers a technical regulation or SPS measure of

general application necessary to address an urgent problem related to the protection of human, plant, or animal health or sanitary or phytosanitary protection. FDA has concluded that this proposed rule is subject to the exception in Executive Order 12889.

The Bioterrorism Act states that it is intended “[t]o improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies.” In order to meet these objectives, section 307 of the Act requires the FDA to propose and issue final regulations requiring prior notice of food imported or offered for import into the United States within 18 months of the Bioterrorism Act’s enactment, which is by December 12, 2003. Section 307 also provides that if FDA does not issue final regulations by this date, FDA still must receive prior notice of food imported or offered for import into the United States by December 12, 2002, of no less than 8 hours and no more than 5 days, subject to compliance with the final regulations when the final regulations are made effective. This expedited timeframe reflects the urgency of the United States government’s need to prepare to respond to bioterrorism and other food-related emergencies and FDA’s need to have the final rule in place, tested, and fully operational by December 12, 2003. This means that the final rule must publish in early October 2003.

FDA will not consider any comments submitted after the 60-day comment period closes and does not intend to grant any requests for extension of the comment period due to the Bioterrorism Act’s requirement to have a final regulation in effect by December 12, 2003, which requires publication on or before October 12, 2003.

## IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

1. Compilation of food entry documents, with corresponding invoices and screens, taken from FDA's Operational and Administrative System for Import Support (OASIS).

2. Bureau of Economic Analysis, <http://www.bea.doc.gov>

3. United States Department of Labor, Bureau of Labor Statistics. National Compensation Survey: Occupation Wages in the United States, 2000. Summary 01–

04. Available at <http://www.bls.gov/ncs/ocs/sp/ncbl0354.pdf>.

4. USDA Agricultural Marketing Service (March 2002) Fresh Fruits and Vegetable Shipments. [www.ams.usda.gov](http://www.ams.usda.gov)

5. Kasmire, Dr. Robert F. Vegetable Marketing Specialist, [www.thepacker.com/rbcs/handbookarticles/properis.htm](http://www.thepacker.com/rbcs/handbookarticles/properis.htm) Accessed on 9.16.02.

6. USDA Agricultural Marketing Service produce point price reports for various border crossings for the dates September 12, 2002 and September 16, 2002. [www.ams.usda.gov](http://www.ams.usda.gov)

7. Florida Department of Agriculture and Consumer Services (FDACS) [www.ffva.com/rps.htm](http://www.ffva.com/rps.htm).

8. National Marine Fisheries Service, Fisheries Statistics and Economics Division, [www.st.nmfs.gov](http://www.st.nmfs.gov) accessed September 2002.

9. Florida Department of Agriculture and Consumer Services, <http://doacs.state.fl.us/press/1999/090999.html> and [www.ffva.com/rps.htm](http://www.ffva.com/rps.htm)

10. Center for Food Safety and Applied Nutrition, <http://www.cfsan.fda.gov/>

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11. Hennessy TW, Hedberg CW, Slutsker L, White KE, Besser-Wiek JM, Moen ME, Feldman J, Coleman WW, Edmonson LM, MacDonald KL, Osterholm MT, and the Investigation Team. A National Outbreak of *Salmonella enteritidis* infections from ice cream. *The New England Journal of Medicine*. May 16, 1996. 1281–1286.

12. Cutler, D., Richardson, E., 1999. Your Money and Your Life: The Value of Health and What Affects It. Working Paper 6895. National Bureau of Economic Research.

13. Zorn, D., Klontz, K., 1998. Appendix: The Value of Consumer Loss to Foodborne Reactive Arthritis”, **Federal Register**, 63, May 1, 1998.

14. Scharff R and A Jessup. Valuing Chronic Disease for Heterogenous Populations: the Case of Arthritis. 2002. Mimeo.

15. Lee LA, Ostroff SM, McGee HB, Johns DR, Downes FP, Cameron DN, Bean NH and PM Griffin. An Outbreak of shigellosis at an outdoor music festival. *American Journal of Epidemiology*. 133:6:608–615.

16. Trook TJ, Tauxe RV, Wise RP, Livengood JR, Sokolow R, Mauvais S, Birkness KA, Skeels MR, Horan JM, and LR Foster. A Large Community Outbreak of Salmonellosis Caused by Intentional Contamination of Restaurant Salad Bars. *JAMA, The Journal of the American Medical Association*, 278:5:389–397.

17. Kolavic SA, Kimura A, Simons SL, Slutsker L, Barth S, and CE Haley. An outbreak of *Shigella dysenteriae* type 2 among laboratory workers due to intentional food contamination. *JAMA, The Journal of the American Medical Association*. 278:5:396–403.

18. Colley DG. Widespread Foodborne Cyclosporiasis Outbreaks Present Major Challenges (letter). *Emerging Infectious Diseases*. 2:4:354–356.

19. Herwaldt BL, Ackers ML, and Cyclospora Working Group. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. *New England Journal of Medicine*. May 29, 1997. 1548–1556.

20. Small Business Administration Office of Advocacy, “Small Business by the Numbers”, May 2002, <http://www.sba.gov/advo/>

## **List of Subjects in 21 CFR Part 1**

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 1 be amended as follows:

## **PART 1—GENERAL ENFORCEMENT REGULATIONS**

1. The authority citation for 21 CFR part 1 continues to read as follows:

**Authority:** 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 304, 321, 331, 334, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

2. Subpart I is added to part 1 to read as follows:

### **Subparts F-G [Reserved]**

### **Subpart I—PRIOR NOTICE OF IMPORTED FOOD General Provisions**

Sec.

1.276 What imported food is subject to this subpart?

1.277 What definitions apply to this subpart?

1.278 What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?



**Requirements to Submit Prior Notice of Imported Food**

Sec.

- 1.285 Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?
- 1.286 When must the prior notice be submitted to FDA?
- 1.287 How must you submit the prior notice?
- 1.288 What information must be submitted in the prior notice?
- 1.289 What changes are allowed to a prior notice after it has been submitted to FDA?
- 1.290 Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?
- 1.291 What is the deadline for product identity amendments under § 1.290?
- 1.292 How do you submit a product identity amendment to a prior notice?
- 1.293 What are the consequences if you do not submit a product identity amendment to your prior notice?
- 1.294 What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?

**General Provisions**

§ 1.276 *What imported food is subject to this subpart?*

(a) This subpart applies to food for humans and other animals that is imported or offered for import into the United States (U.S.), including U.S. foreign trade zones, for consumption, storage, immediate export from the port of entry, transshipment through the United States to another country, or import for export.

(b) This subpart does not apply to:

(1) Food that is carried by an individual entering the United States in that individual's personal baggage for that individual's personal use;

(2) Meat food products that at the time of importation are subject to the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*);

(3) Poultry products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*); and

(4) Egg products that at the time of importation are subject to the exclusive jurisdiction of USDA under the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*).

§ 1.277 *What definitions apply to this subpart?*

(a) The act means the Federal Food, Drug, and Cosmetic Act.

(b) The definitions of terms in section 201 of the act (21 U.S.C. 321) apply when the terms are used in this subpart.

(c) In addition, for the purposes of this subpart:

(1) *Calendar day* means every day shown on the calendar.

(2) *Country from which the article of food was shipped* means the country in which the article of food was loaded onto the conveyance that brings it to the United States.

(3) *Food* has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to, fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food, dietary supplements and dietary ingredients, infant

formula, beverages, including alcoholic beverages and bottled water, live food animals, bakery goods, snack foods, candy, and canned foods.

(4) *Originating country* means the country from which the article of food originates. If the article of food is fresh produce or fresh aquacultured fish or seafood, the originating country is the country in which it is grown and harvested. If the article of food is wild-caught fish or seafood and it is harvested in the waters of the United States or by a U.S. flagged vessel or processed aboard a U.S. flagged vessel, the originating country is the United States. Otherwise, the originating country is the country in which the article of food is produced.

(5) *Port of entry* means the water, air, or land port at which the article of food is imported or offered for import into the United States, i.e., the port where food first arrives in the United States. This port may be different than the port where the article of food is entered for U.S. Customs Service purposes.

(6) *You* means the purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer or, if the article of food is imported with the intention of in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier.

§ 1.278 *What are the consequences of failing to submit adequate prior notice or otherwise failing to comply with this subpart?*

(a) If an article of food is imported or offered for import with no prior notice or inadequate (e.g., untimely, inaccurate, or incomplete) prior notice,

the food shall be refused admission under section 801(m)(1) of the act (21 U.S.C. 381(m)(1)).

(b) If an article of food is refused admission under section 801(m)(1), it must be held at the port of entry unless FDA directs its removal to a secure facility in accordance with § 1.278(c).

(c) If FDA determines that removal to a secure facility is appropriate (e.g., due to a concern with the security of the article of food or due to space limitations in the port of entry), FDA may direct that the article of food be removed to a Bonded Warehouse, Container Freight Station, Centralized Examination Station, or another appropriate secure facility that has been approved by FDA.

(d) The person submitting the prior notice or the carrier must arrange for movement of the article of food, under appropriate custodial bond, within the port of entry or to the secure facility and must promptly notify FDA of the location. Transportation and storage expenses shall be borne by the owner, purchaser, importer, or consignee.

(e) (1) The article of food must be held at the port of entry or in the secure facility until prior notice is submitted to FDA in accordance with this subpart, FDA has examined the prior notice, FDA has determined that the prior notice is adequate, and FDA has notified the U.S. Customs Service and the person who submitted the prior notice that the article of food no longer is subject to refusal of admission under section 801(m)(1) of the act.

(2) Notwithstanding section 801(b) of the act (21 U.S.C. 381(b)), while any article of food that has been refused admission under section 801(m)(1) of the act is held at its port of entry or in a secure facility, it may not be delivered to any of its importers, owners, or consignees.

(f) A determination that an article of food is no longer subject to refusal under section 801(m)(1) is different than, and may come before, determinations of admissibility under other provisions of the act or other U.S. laws. A determination that an article of food is no longer subject to refusal under section 801(m)(1) does not mean that it will be granted admission under other provisions of the act or other U.S. laws.

(g) Any person who imports or offers for import an article of food without complying with the requirements of 21 U.S.C. 381(m) as set out in this subpart, or otherwise violates any requirement under 21 U.S.C. 381(m), or any person who causes such an act, commits a prohibited act within the meaning of 21 U.S.C. 331 (ee). Under 21 U.S.C. section 332, the United States can bring a civil action in Federal court to enjoin persons who commit prohibited acts. Under 21 U.S.C. section 333, the United States can bring a criminal action in Federal court to prosecute persons who commit prohibited acts. Under 21 U.S.C. 335a, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States.

### **Requirements to Submit Prior Notice of Imported Food**

§ 1.285 *Who is authorized to submit prior notice for an article of food that is imported or offered for import into the United States?*

(a) A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer, is authorized to submit to FDA prior notice of the article of food being imported or offered for import into the United States, except as specified in paragraph (b) of this section.

(b) If the article of food is imported for in-bond movement through the United States for export, i.e., Transportation for Exportation or Immediate Export entries, the arriving carrier or, if known, the in-bond carrier is authorized to submit prior notice to FDA.

*§ 1.286 When must the prior notice be submitted to FDA?*

(a) You must submit the prior notice to FDA no later than noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry.

(b) You may not submit the prior notice until all of the information required by § 1.288 exists, except as provided in §§ 1.288(e)(2) and 1.290, which both relate to product identity amendments. You may not submit prior notice more than 5 days before the anticipated date of arrival of the food at the anticipated port of entry.

*§ 1.287 How must you submit the prior notice?*

(a) You must submit prior notice, product identity amendments, and arrival updates electronically to FDA through FDA's Prior Notice System, which is available at [www.fda.gov/](http://www.fda.gov/)\_\_, except as provided in paragraph (b) of this section.

(b) If FDA's Prior Notice System is unable to receive prior notice electronically, you must submit prior notice, product identity amendments, and arrival updates using a printed version of the Prior Notice Screen from FDA's Prior Notice System delivered in person, by e-mail, or fax to the FDA field office with responsibility over the geographical area in which the anticipated port of entry identified in your initial prior notice is located.

*§ 1.288 What information must be submitted in the prior notice?*

For each article of food that is imported or offered for import into the United States, you must submit the information listed below:

(a) The name of the individual submitting the prior notice, the submitting firm's name, address, phone number, fax number, and e-mail address, and, if the firm is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(b) The entry type as designated by the U.S. Customs Service;

(c) The U.S. Customs Service's Automated Commercial System (ACS) entry number, or if the article of food is an import that is not subject to ACS, the other U.S. Customs Service identification number associated with the importation;

(d) If the article of food is under hold under § 1.278, the location where it is being held, the date the article will arrive at that location, and identification of a contact at that location.

(e)(1) The identity of the article of food being imported or offered for import, as follows:

(i) The complete FDA product code;

(ii) The common or usual name or market name;

(iii) The trade or brand name, if different from the common or usual name or market name;

(iv) The quantity of food described from smallest package size to largest container; and

(v) The lot or code numbers or other identifier of the food if applicable.

(2) If all of the information required by this subsection exists by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must include it in your prior notice and

you may not amend the prior notice under § 1.290. If any of this information does not exist by noon of the calendar day before the day the article of food will arrive at the border crossing in the port of entry, you must give FDA as much information as does exist at that time and tell FDA that you will amend the prior notice as required under § 1.290.

(f) The name, address, phone number, fax number, and e-mail address of the manufacturer, and if it is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(g) The name, address, phone number, fax number, and e-mail of all growers, and the growing location if different from business address, if known at time of submission of your prior notice;

(h) The originating country of the article of food;

(i) The name, address, phone number, fax number, and e-mail address of the shipper and, if it is required to register under 21 CFR part 1, subpart H, for a facility associated with the article of food, the registration number assigned to that facility;

(j) The country from which the article of food was shipped;

(k) (1) Anticipated arrival information about the article of food being imported or offered for import, as follows:

(i) The anticipated port of entry and, if the anticipated port of entry has more than one border crossing, the specific anticipated border crossing where the food will be brought into the United States;

(ii) The anticipated date on which the article of food will arrive at the anticipated port of entry; and

(iii) The anticipated time of that arrival;



(2) If any of the anticipated arrival information required under this paragraph changes after you submit your prior notice, you must update your notice in accordance with § 1.294.

(l) The port where entry of the article of food will be made for purposes of the U.S. Customs Service;

(m) The anticipated date of entry for purposes of the U.S. Customs Service; and

(n) The name, address, phone number, fax number, and e-mail address of the importer, and, if the importer is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(o) The name, address, phone number, fax number, and e-mail address of the owner, and if the owner is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility;

(p) The name, address, phone number, fax number, and e-mail address of the consignee, and if the consignee is required to register for a facility associated with the article of food under 21 CFR part 1, subpart H, the registration number assigned to that facility; and

(q) The names, addresses, phone numbers, fax numbers and e-mail addresses of all the carriers which are or will be carrying the article of the food from the country from which the article of food was shipped to the United States, and the carriers' Standard Carrier Abbreviation Codes (SCAC) if appropriate.

The Prior Notice Screen of FDA's Prior Notice System also identifies the information that you must submit to FDA.

§ 1.289 *What changes are allowed to a prior notice after it has been submitted to FDA?*

After a prior notice has been submitted to FDA, it may only be changed as set out in § 1.290 which relates to product identity amendments or § 1.294 which relates to arrival updates. If other information provided in the prior notice changes, you must cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA.

§ 1.290 *Under what circumstances must you submit a product identity amendment to your prior notice after you have submitted it to FDA?*

(a) If any of the information required by § 1.288(e)(1) did not exist at the time you submitted your prior notice and the prior notice you submitted was therefore incomplete, you must amend your prior notice with complete

product identity information by the deadline specified in § 1.291.

(b) You may only amend your prior notice once.

(c) You may not change the general identity of the article of food that is the subject of the prior notice by amendment. However, if the article is fresh produce or fresh, wild-caught fish, you may amend the last two digits of the product code when you do not know the specific identity of the article at the time of initial prior notice. If your initial prior notice submission identifies the product by the FDA product code for “fresh peppers, refrigerated,” when you amend your submission, you must give the product code that identifies with specificity the type of pepper—“fresh green bell peppers, refrigerated.” You may also include more than one article in your amendment if the industry and class and process (of the FDA product code) are the same. A prior notice for “refrigerated fresh fish” may be amended as “refrigerated fresh cod” and “refrigerated fresh salmon,” but not “refrigerated fresh cod” and “canned

shrimp.” You may not amend the product identity to refer to another food, e.g., apples, or another process, e.g., canned.

(d) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you submit a product identity amendment to your prior notice, you must include in your amendment: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

§ 1.291 *What is the deadline for product identity amendments under § 1.290?*

Your product identity amendment must be submitted no later than

~~(a)~~ 2 hours prior to the time of arrival.

§ 1.292 *How do you submit a product identity amendment to a prior notice?*

You must submit product identity amendments in accordance with

§ 1.287.

§ 1.293 *What are the consequences if you do not submit a product identity amendment to your prior notice?*

(a) If you informed FDA in your prior notice that you would be submitting a product identity amendment but you do not amend your prior notice completely, the prior notice is inadequate for the purposes of § 1.278(a).

(b) If you informed FDA in your prior notice that you would be submitting a product identity amendment and you submit your amendment after the deadline provided in section 1.291, the prior notice is inadequate for the purpose of § 1.278(a).

§ 1.294 *What must you do if the anticipated arrival information (required under § 1.288(k)(1)) submitted in your prior notice changes?*

(a) If any of the anticipated arrival information required under § 1.288(k)(1)

changes after you submit a prior notice to FDA, you must submit an arrival update updating the information in your prior notice in accordance with § 1.287. Your arrival update must provide the following information:

(1) If the anticipated port of entry changes, provide the updated port of entry;

(2) If the time of arrival is expected to be more than 3 hours later than the anticipated time of arrival, provide the updated time of arrival;

(3) If the time of arrival is expected to be more than 1 hour earlier than the anticipated time of arrival, provide the updated time of arrival.

(b) If you did not provide grower identity at the time you submitted your prior notice under this subpart, but you know the identity of the grower when you update your prior notice, you must include in your update: the name, address, phone number, fax number, and e-mail of all growers, and growing location if different from business address.

(c) You must update the information in accordance with the requirements of §§ 1.291 and 1.292.

(d) If you do not submit an arrival update when one is required by paragraph (a) of this section, the prior notice is inadequate for the purposes of § 1.278(a).

Dated: \_\_\_\_\_

\_\_\_\_\_

Dated: \_\_\_\_\_

Note: The following form is an appendix that will not appear in the Code of Federal Regulations.

[INSERT GLOSSY]

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**